IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, et al.	:	CIVIL ACTION
	:	No. 13-4663
v.	:	
GLAXOSMITHKLINE LLC	:	

MEMORANDUM

Juan R. Sánchez, C.J. **September 30, 2019**

Plaintiffs, 38 private health insurance companies that purchased billions of dollars' worth of adulterated pharmaceutical drugs from Defendant GlaxoSmithKline LLC (GSK), bring the instant action, alleging they purchased the drugs at issue based on GSK's misrepresentations that the drugs were manufactured in accordance with the Food and Drug Administration's "current Good Manufacturing Practices."[1] Plaintiffs claim the adulterated drugs were worthless and had they known of the adulteration they would not have included the drugs in their formularies. GSK has moved to exclude Plaintiffs' five expert witnesses pursuant to Federal Rule of Evidence 702—Phillip Russ; David A. Kessler, M.D.; Matthew Perri III, B.S. Pharm, PhD, RPh; Stephen W. Schondelmeyer, PhD; and Rena Conti, PhD. GSK's motion will be granted insofar as Dr. Kessler will be precluded from defining "material impact" or referring to certain cGMP violations as having a "material impact" during his testimony at trial, and Dr. Schondelmeyer will be excluded from testifying at trial. The balance of the Motion will be denied.

[1] At the time of filing, 41 private health insurance companies were named as plaintiffs in this action. Since filing, three plaintiffs—Blue Cross of Idaho Health Service, Inc., Health Care Services Corporation, and Horizon Blue Cross Blue Shield of New Jersey—have settled with GSK.

BACKGROUND

This case arises out of Plaintiffs' providing prescription drug coverage for seventeen drugs—Albenza, Avandia, Avandamet, Bactroban, Compazine, Coreg, Denavir, Dibenzyline, Dyazide, Dyrenium, Factive, Horowitz, Kytril, Paxil IR, Paxil OS, Stelazine, and Thorazine (collectively, the At-Issue Drugs). The drugs were manufactured by GSK's corporate affiliate, SB Pharmco Puerto Rico Inc. (SB Pharmco), at a pharmaceutical manufacturing plant in Cidra, Puerto Rico (the Cidra Plant). From 2000 to 2005 (the Relevant Period), Plaintiffs assert SB Pharmco's poor manufacturing process and quality control system at the Cidra Plant were non-compliant with the Food and Drug Administration's (FDA) "current Good Manufacturing Practices" (cGMP). According to Plaintiffs, the drugs were therefore "adulterated" under the Food, Drug & Cosmetic Act (FDCA). *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). Plaintiffs allege GSK fraudulently misrepresented that the At-Issue Drugs manufactured at the Cidra Plant were cGMP compliant, resulting in Plaintiffs providing coverage for adulterated drugs they claim were worthless.[2] In support of their case, Plaintiffs have retained the five expert witnesses.

Plaintiffs retained Philip Russ to analyze the nature and extent of the cGMP violations at the Cidra Plant during the Relevant Period. *See* Pls.' Resp. in Opp'n to Def.'s *Daubert* Mot. (Pls.' Opp'n) 2. Russ is the owner and president of Innovative Consultants GXP, which "provides a range of regulatory compliance and quality assurance services to clients in the pharmaceutical, medical device, and biologics industry." GSK's Mot. to Exclude Expert Test. of Phillip Russ, Drs. David Kessler, Matthew Perri, Stephen Schondelmeyer, and Rena Conti (GSK Mot.) Ex. 3, at 4. Russ has twenty-three years of experience in the pharmaceutical, medical device, and biologics

[2] In light of the Court having provided a detailed recitation of the facts of this case in its September 30, 2019, Memorandum granting in part and denying in part GSK's Motion for Summary Judgment, the Court will not further discuss the factual background of this case.

industry, focusing on the regulatory compliance aspects of developing and managing quality management systems and cGMP compliance. *See id.* Russ's report evaluates "the extent to which manufacturing at the [Cidra Plant] was in material violation of 21 U.S.C. § 351." *Id.* at 3. Russ's report is based upon a review of (1) cGMP records of compliance activities; (2) FDA inspection results; (3) GSK's internal audits; (4) internal GSK emails and other correspondence and memoranda related to the Quality Management System (QMS) at the Cidra Plant; and (5) the observations of Quantic Regulatory Services, the third-party expert engaged by GSK to evaluate cGMP compliance at the Cidra Plant as a result of a Consent Decree entered into between GSK and the FDA. *Id.* at 3-4. After review of these documents, Russ concluded "all products manufactured at the Cidra Plant between 2000 and 2005 were materially non-compliant with cGMPs and lacked the assurance of conformance to their represented properties." *Id.* at 105.

Plaintiffs retained David A. Kessler, M.D., as an expert on cGMP regulations and cGMP compliance. Dr. Kessler was FDA Commissioner from 1990 until 1997. *See id.* Ex. 7, at ¶ 2 As the FDA Commissioner, Dr. Kessler oversaw the FDA's promulgation and implementation of proposed and finalized regulations concerning cGMPs for pharmaceuticals. *See id.* at ¶ 5-7. Dr. Kessler's expert report opines on four central questions: (1) "[w]hy is compliance with cGMPs important?"; (2) "[w]hy are a drug manufacturer's responsibilities with regard to cGMP compliance?"; (3) "[f]rom a regulatory point of view, what types of cGMP violations can have a 'material impact' on a drug?"; (4) "[i]f specific drugs are recalled from the market or seized from a plant because they violate cGMPs, what conclusions can be drawn as to whether other drugs at the same plant are cGMP compliant?" *id.* at ¶ 11(a)-(d). Dr. Kessler opines that (A) cGMP compliance is important "because it assures that what a drug manufacturer says is in a drug is actually in the drug;" *id.* at ¶ 12, (B) drug manufacturers "[can]not sell products that fall below the

represented standards," *id.* at ¶ 28, and must "investigate, understand, and correct quality deviations," *id.* at ¶ 30, (C) there "are three categories of cGMP violations that can have a 'material impact' on a drug," *id.* at ¶ 35, and (D) "[t]he fact that specific drug products are recalled from the market or seized from a plant because they violate cGMPs does not mean that other drugs are cGMP-compliant," *id.* at ¶ 43.

Matthew Perri III, B.S. Pharm, PhD, RPh, is offered as an expert in pharmaceutical marketing and his expert report assesses "the nature and significance of the marketing activities of [GSK] related to ongoing problems at [the Cidra Plant]." *Id.* Ex. 8, at 3. Dr. Perri is a Professor at the University of Georgia, teaching undergraduate and graduate courses in healthcare and pharmaceutical marketing and other related areas. *See id.* at ¶ 1-3. Dr. Perri offers seven opinions including, inter alia, (1) it is the pharmaceutical manufacturer's job to ensure its drug products are manufactured in compliance with all FDA regulations; (2) patients, pharmacists, prescribers, and third-party payers rely on the assurance that a drug is what the manufacturer represents it to be; (3) major pharmaceutical manufacturers control the information their personnel disseminate into the market place; and (4) it is not feasible, or expected, for third-party payers to monitor FDA enforcement actions, given the number of drugs listed on third-party payers' formularies. *See id.* at 3. In reaching his conclusions, Dr. Perri asserts his opinions are based on "universally accepted principles of marketing." *Id.* at ¶ 11.

Next, Plaintiffs offer Stephen Schondelmeyer, PhD, as a causation expert to demonstrate that, had Plaintiffs known about the cGMP violations at the Cidra Plant, they would have removed the At-Issue Drugs from their formularies and that non-cGMP compliant drugs have no economic value to third-party payors. Dr. Schondelmeyer is a Professor of Pharmaceutical Management and Economics at the University of Minnesota. *See id.* Ex. 11, at ¶¶ 1, 4. Dr. Schondelmeyer has more

than 40 years of experience related to pharmaceutical economics and public policy research. *See id.* at ¶ 4. In his six-page opinion, Dr. Schondelmeyer concludes, based on his experience, "no payer in the United States would knowingly and willingly pay for such material non-compliant drugs [and] [s]uch drug products for all practical purposes have no value in the U.S. market and would be considered non-salable." *Id.* at ¶ 19.

Finally, Plaintiffs offer Rena Conti, PhD, as an expert on damages. Dr. Conti is an Associate Professor at Boston University's Questrom School of Business and an economist for the FDA's Center for Drug Evaluation and Research. *See id.* Ex. 15, at ¶ 8. She focuses her research on the market for prescription drugs and the pricing of pharmaceutical products in the United States market. *See id.* at ¶ 10. Dr. Conti concludes only prescription drugs "manufactured in compliance with [cGMPs] may be assigned a non-zero value by patients and third-party payers, and drugs which fail to meet those standards have no economic value." *Id.* at ¶ 4. Applying the economic principle of supply and demand, Dr. Conti concluded there can be no legitimate supply curve to establish an economic value because the FDCA prohibits the sale of adulterated drugs. *See id.* at ¶ 37-40. Dr. Conti further determined that, "[b]ecause GSK produced and sold non-compliant drugs, plaintiffs paid for illegitimate products that have no economic value." *Id.* at ¶ 5. As a result, Dr. Conti calculated the aggregate damages for all Plaintiffs as $2.82 billion, and individual damages for each Plaintiff as ranging between $3.3 million to $483.7 million. *See id.* at ¶ 52.

DISCUSSION

Federal Rule of Evidence 702 governs the admissibility of expert testimony. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) that testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

The United States Supreme Court stated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, that Rule 702 creates a "a gatekeeping role for the [trial] judge." 509 U.S. 579, 597 (1993). However, "the court's role as a gatekeeper is not intended to serve as a replacement for the adversary system," because, "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Crowley v. Chait*, 322 F. Supp. 2d 530, 536 (D. Del. 2004) (internal quotation marks and alterations omitted).

Following *Daubert*, the Third Circuit Court of Appeals has explained that Rule 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). The party offering the expert evidence bears the burden of establishing its admissibility by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999). Rule 702 envisions a "liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). GSK does not seek to exclude Plaintiffs' experts based on their qualifications and this requirement will therefore not be further discussed.

To meet the "reliability" requirement, "a litigant has to make more than a prima facie showing that his expert's methodology is reliable . . . [but] the evidentiary requirement of reliability is lower than the merits standard of correctness." *Pineda*, 520 F.3d at 244. The expert's opinion

"must be based on the methods and procedures rather than on 'subjective belief or unsupported speculation.'" *In re TMI Litig.*, 193 F.3d 613, 664 (3d Cir. 1999) (citation omitted). The Court must focus on the expert's methodology—not his or her conclusions. *In re Paoli R.R. Yard PCB Lit.*, 35 F.3d 717, 746 (3d Cir. 1994) ("[T]he issue is whether the evidence should be excluded because the flaw is large enough that the expert lacks good grounds for his or her conclusions.")

When evaluating the reliability of a witness's methodology, the Court is guided by several factors drawn from *Daubert*:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

id. at 742 n.8. The Rule 702 inquiry is a flexible one, and the court should also take into account any other relevant factors. *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003).

To meet the "fit" requirement "the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Schneider*, 320 F.3d at 404. Like a typical relevance inquiry, the standard for analyzing the fit of an expert's analysis is "not that high." *United States v. Ford*, 481 F.3d 215, 219-20 (3d Cir. 2007). Nevertheless, expert testimony can be powerful and misleading, and the Third Circuit has cautioned district courts to "tread carefully when evaluating proffered expert testimony." *Id.* at 219 n.6. With these standards in mind, the Court turns to GSK's motion to exclude.

GSK first moves to exclude Russ's testimony arguing it does not fit the question before the Court. GSK contends the question before the Court is whether Plaintiffs can prove that GSK's

cGMP violations had a "material impact" on the drugs for which they paid. GSK asserts Russ proposes to testify only that GSK could not assure that the At-Issue Drugs were not impacted by the cGMP violations at the plant. GSK claims such testimony would confuse the jury and is irrelevant. GSK's argument is unpersuasive.

In denying GSK's motion to dismiss, this Court previously held "Plaintiffs [were] entitled prove that the nature of GSK's [cGMP] violations had a material impact on the drugs for which they paid." *See* Mem. 11, Nov. 9, 2016, ECF No. 105. Russ's report finds the Cidra Plant had significant fundamental failures in all six essential quality systems—which relate to a manufacturer's ability to certify a drug's purity, uniformity, quality, and manufacturing. The report concludes that, due to these chronic failures, GSK could not assure the At-Issue Drugs "conformed to their represented properties of safety, identity, strength, purity, and quality." GSK Mot. Ex. 4, at 9. This testimony fits the question in this case and is relevant because a reasonable jury could find GSK's cGMP violations had a material impact on the value of the At-Issue Drugs as GSK could not assure their conformance to their representative properties—i.e., their quality was not as labeled and advertised.

GSK also argues Russ's opinion fails the reliability test because (1) his opinion applies to every product made at the Cidra plant during the relevant time period, not just the At-Issue Drugs; (2) he has never used the phrase "material violation" before this litigation and it does not have the same meaning as "material impact"; and (3) he could not answer why the FDA chose to seize a certain drug manufactured at the Cidra Plant but concurrently stated consumers could continue to take another drug manufactured at the Cidra Plant with confidence. These arguments, however, go to the weight and credibility of Russ's testimony and can be explored through "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof."

Crowley, 322 F. Supp. 2d at 536. Therefore, GSK's motion to exclude Russ's testimony will be denied.

GSK next moves to exclude Dr. Kessler's expert opinion asserting it draws an impermissible legal conclusion. GSK contends Dr. Kessler's opinion is merely a legal conclusion because he seeks to interpret the "material impact" language from the Court's November 9, 2016, Memorandum. GSK argues this is a legal term the Court must instruct the jury on, and therefore, Dr. Kessler may not opine on it.

GSK's motion to exclude Dr. Kessler's testimony will be granted insofar as Dr. Kessler will prohibited from defining "materiality" or referring to certain cGMP violations as having a "material impact." Quoting the Court's November 9, 2016, Memorandum, Dr. Kessler seeks to opine on "what types of cGMP violations have a 'material impact' on a drug" and interpret the language in the Court's Memorandum. *See* GSK Mot. Ex. 8, at 2 ("The Court in this case cited the FDA's statement, then noted that Plaintiffs are entitled to show a "material impact" on drugs for which they paid. From a regulatory point of view, what types of cGMP violations can have a "material impact" on a drug?"). Allowing Dr. Kessler to opine on what constitutes a material impact on the case would run afoul of *Daubert* as it would allow Dr. Kessler to directly opine on the legal issue in this case. *See Whitmill v. City of Philadelphia*, 29 F. Supp. 2d 241, 246 (E.D. Pa. 1998)("As a general rule an expert's testimony on issues of law is inadmissible.")(quoting *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991)); *see also In re Wellbutrin SR Antitrust Lit.*, Nos. 04-5525, 05-5898, 05-396, 2010 WL 8425189, at *3-5 (E.D. Pa. Mar. 31, 2010) (collecting cases and finding the experts in the instant case could testify about the background of patent law and procedure but could not testify about whether a previous patent lawsuit was objectively baseless—a legal issue in the case). Therefore, Dr. Kessler will be precluded from

defining "material impact." However, Dr. Kessler will be permitted to testify about FDA regulations generally and how cGMP violations occur on a spectrum, including how violations range in severity and provide examples of how cGMP violations fall on that spectrum.[3] Therefore, GSK's motion to exclude Dr. Kessler's testimony will be granted insofar as Dr. Kessler will prohibited from defining "materiality" or referring to certain cGMP violations as having a "material impact" during his testimony at trial.[4]

Next, GSK moves to exclude Dr. Perri's testimony based on reliability.[5] GSK argues Dr. Perri's opinion must be excluded because he fails to explain or define the reliable methodology he used to come to his opinion. Specifically, GSK asserts Dr. Perri explains he applied "universally accepted principles of marketing," *see* GSK Mot. Ex. 8, at ¶ 11, but never defined the principles,

[3] GSK also moves to exclude Dr. Kessler's opinion on what constitutes a "material impact" because there is no FDA practice or policy grounding his opinion. However, because the Court will prevent Dr. Kessler from defining "material impact," GSK's argument is moot.

[4] GSK directs the Court to a handful of cases, which it asserts demonstrate that Dr. Kessler's testimony has regularly been excluded. However, in the majority of the cases GSK relies on, Dr. Kessler's testimony was not excluded but merely narrowed. *In re Bard IVC Filters Prods. Liab. Litig.*, No. 15-02641, 2017 WL 6523833, at *9 (D. Ariz. Dec. 21, 2017) ("Dr. Kessler is qualified to opine on FDA regulatory issues that relate to Bard filters, and his testimony in this regard would prove helpful to the jury. But no expert, including Dr. Kessler, will be permitted to give ultimate legal opinions on state law claims, improperly narrate or regurgitate facts, or speculate about motives or intent."); Order, *Bartolini v. Abbott Labs., Inc.*, No. 15-702 (S.D. Ill. May 23, 2017), ECF No. 277 (granting in part and denying in part motion to exclude Dr. Kessler's testimony); *In re Prograf Antitrust Litig.*, No. 11-2242, 2014 WL 7641156, at *2-3 (D. Mass. Dec. 23, 2014) (granting in part and denying in part motion to exclude Dr. Kessler's testimony); *Drake v. Allergan, Inc.*, No. 13-234, 2014 WL 5392995, at *5-6 (D. Vt. Oct. 23, 2014) ("Allergan's Motion [to exclude Dr. Kessler's testimony] is granted to the extent it sought the general guidance given above and denied to the extent that some objections will have to be raised at trial"); *Allen v. Takeda Pharm. N.A., Inc.*, Nos. 11-2299, 12-64, 2014 WL 120973, at *4-19 (W.D. La. Jan. 10, 2014) (granting in part and denying in part motion to exclude Dr. Kessler's testimony); *Wells v. Allergan*, No. 12-973, 2013 WL 7208221, at *2 (W.D. Okla. Feb. 4, 2013) (allowing defendants to object at trial if Dr. Kessler speculates or regurgitates facts).

[5] GSK's motion to exclude also states GSK seeks to exclude Dr. Perri's testimony on the basis of fit. *See* GSK Mot. 1. GSK's arguments, however, all pertain to the reliability of Dr. Perri's opinion.

applied specific principles, or explained why these principles would assist the jury in determining whether Plaintiffs would have removed the At-Issue Drugs from its formularies.

GSK's arguments are unpersuasive. While GSK focuses on the phrase "universal principles of marketing" to argue Dr. Perri's analysis is unreliable, Dr. Perri applies the case study method—an objective methodology—and consults additional academic sources regarding the pharmaceutical industry, to apply his own pharmaceutical and healthcare marketing experience to the facts of the instant case and draw his conclusions. *See generally id.* ¶ 13-75. As other courts have held, this is sufficient to meet the reliability prong under *Daubert*. *See Wolfe v. McNeil–PPC, Inc.*, No. 07–348, 2011 WL 1673805, at *5 (E.D. Pa. May 4, 2011) (finding three doctor's testimony sufficiently reliable where the doctors used the case study method and "extensive[ly] review[ed] of plaintiff's medical records and deposition testimony of plaintiff's treating physicians" and determined "the three doctors' use of case studies in reaching their conclusion affects only the weight to be given their testimony, not its admissibility. . . ."); *Acosta v. WPN Corp.*, No. 14-1494, 2018 WL 3707418, at *6 (W.D. Pa. Aug. 3, 2018) (admitting expert testimony where the expert used "her experience and specialized knowledge" to discern a standard of fiduciary care and apply it to the facts of the case). In any event, the issues GSK takes with Dr. Perri's analysis pertain to the credibility and weight of Dr. Perri's testimony, which GSK may test through cross-examination and the presentation of contrary evidence. *See Crowley*, 322 F. Supp. 2d at 536.

GSK further asserts Dr. Perri's expert opinion should be excluded because it is similar to the excluded opinion he offered in *United States v. AseraCare, Inc.*, No 12-0245, 2014 WL 6879254, at *1 (N.D. Ala. Dec. 4, 2014). In *AseraCare*, the Government sought to offer Dr. Perri as a "marketing expert" to support its theory that an operator of hospice facilities knew it had

submitted false Medicare claims. *Id.* at *11. To support his opinion, Dr. Perri relied on "universal principles of marketing." *Id.* at *12. The court ultimately excluded Dr. Perri's opinion, stating "Dr. Perri has no experience in the hospice industry, did not study any other hospice companies, and did not review any of the guidance from [the Centers for Medicare and Medicaid Services] regarding many of the topics on which he opined." *Id.* at *11. GSK contends *AseraCare* is nearly identical to this case, and the Court should therefore exclude Dr. Perri's testimony on the same grounds.

GSK's reliance in *AseraCare* is misplaced. Dr. Perri's opinion in *AseraCare* was excluded because he did not have *any* experience in the hospice industry and failed to explain why his universal principles of marketing methodology had any bearing in the hospice industry. *Id.* at *12. Unlike *AseraCare*, in the instant case, Dr. Perri has significant experience in the pharmaceutical marketing industry—a point which GSK does not dispute. *See* GSK Mot. Ex. 7, at ¶ 1-11 (discussing Dr. Perri's qualifications). Further, unlike *AseraCare*, Dr. Perri has connected his "universally accepted principles of marketing" to the pharmaceutical industry. *See id.* at ¶ 13-17 (describing marketing principles generally and how they apply in the pharmaceutical market). Therefore, the reasons for excluding Dr. Perri's testimony in *AseraCare* do not apply and GSK's motion to exclude Dr. Perri's testimony will be denied.

Turning Dr. Schondelmeyer, GSK argues Dr. Schondelmeyer's testimony should be excluded because it is unreliable. GSK asserts Dr. Schondelmeyer's report states he provided his opinion as an "expert on economic and public policy issues," GSK Mot. Ex. 11, at ¶ 1, but when deposed he stated his opinion was "not really" economic in nature, *id.* Ex. 12, at 176:18-20. GSK further contends Dr. Schondelmeyer failed to tie his expert opinion to the facts of the case by

failing to cite any source for his key opinions. The Court agrees with GSK and finds Dr. Schondelmeyer has failed to offer a reliable methodology as the basis for his opinion.

Initially, the type of expert analysis Dr. Schondelmeyer purports to provide is unclear. In his report, Dr. Schondelmeyer states he provides his opinion as an "independent expert on economic and public policy issues." GSK Mot. Ex. 11, at ¶ 1. However, in his deposition, he stated his opinion provides no economic analysis. *See id.* Ex. 12, at 176:18-20. Yet, in his reply report, Dr. Schondelmeyer states his opinion is that non-cGMP-compliant drugs have "no economic value," *id.* Ex. 13, at ¶ 5 ("Under federal law, materially non-compliant drugs cannot be lawfully distributed and sold. For payers acting within the law, therefore, such drugs have no economic value." (footnote omitted)). Adding further confusion is Plaintiffs' presentation of Dr. Schondelmeyer as a "healthcare insurance expert." *See* Pls.' Resp. in Opp'n to Def.'s Mot. for Summ. J. 17 ("Dr. Stephen Schondelmeyer (Plaintiffs' healthcare insurance expert)."). The Court is hard pressed to find an acceptable basis on which to allow Dr. Schondelmeyer to testify about non-cGMP-compliant drugs having "no economic value" while claiming he is not providing an economic analysis and being offered as a healthcare expert.

In any event, Dr. Schondelmeyer provides no reliable basis for his opinions. In two brief paragraphs of his short six-page report, Dr. Schondelmeyer concludes that, based on his experience, insurers rely on a drug manufacturer's assurances regarding cGMP compliance and no insurer or third-party payer would pay for drugs with material cGMP violations. *See* GSK Mot. Ex. 11, at ¶ 18-19. Dr. Schondelmeyer's opinion, however, provides no more than a paradigm example of "say-so" expert testimony. While the Court does not doubt his qualifications and experience in the pharmaceutical industry, Dr. Schondelmeyer has failed to demonstrate or explain how his experience is reliably applied to the facts of this case. *See id.* ("My experience includes

consulting for payers that provide drug benefits to insured individuals or beneficiaries, including, but not limited to, self-insured employers . . . In my experience, no payer in the United States would knowingly and willingly pay for such materially non-compliant drug products."). Unlike Dr. Perri, whose experience-based testimony was applied to the instant case through the objective case study methodology and supplemented with additional academic sources, Dr. Schondelmeyer's experience-based testimony is *entirely subjective* and premised solely on his say-so, which cannot be adequately tested through cross-examination. *In re TMI Lit.*, 193 F.3d at 703 n.144 ("[I]t is impossible to test a hypothesis generated by a subjective methodology because the only person capable of testing or falsifying the hypothesis is the creator of the methodology."). The Court will therefore grant GSK's motion to exclude Dr. Schondelmeyer's testimony. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."); *see also Player v. Motiva Enters., LLC*, 240 F. App'x 513, 520 (3d Cir. 2007) (stating the "District Court certainly had the discretion to exclude opinion evidence that is connected to existing data only by the ipse dixit [or say-so] of the expert." (internal citations omitted)).

Finally, GSK moves to exclude Dr. Conti's expert testimony on four grounds: (1) she impermissibly bases her opinion on a legal interpretation of the FDCA; (2) she provides no reliable economic methodology for her opinion; (3) she improperly regurgitates Plaintiffs' allegations; and (4) she fails to account for the rebates Plaintiffs received for purchasing the At-Issue Drugs and fails to consider the cost of alternative treatment options. GSK's arguments to exclude Dr. Conti's testimony are unavailing.

First, Dr. Conti's testimony does not render an impermissible legal conclusion. Dr. Conti's expert report states the FDCA prevents companies from introducing adulterated drugs into the market place. *See* 21 U.S.C. § 331(a) ("The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."). According to Dr. Conti, based on this prohibition, economic principles state there is no legitimate supply curve for these drugs. *See, e.g.*, GSK Mot. Ex. 15, at ¶¶ 4, 38, 39. Because Dr. Conti is explaining the FDCA's prohibition on adulterated drugs—based on her own previous experience and discussions with pharmaceutical companies—and not providing a legal conclusion, she is not rendering an impermissible legal opinion. *See Hartle v. FirstEnergy Gen. Corp.*, Nos. 08–1019, 08–1025, 08–1030, 2014 WL 5089725, at *1-2 (W.D. Pa. Oct. 9, 2014) (permitting an expert to explain regulations but not offer an opinion on whether the defendant violated the provisions at issue).

Second, GSK's argument that Dr. Conti's expert opinion is not based on a reliable economic methodology is similarly without merit. As her expert report demonstrates, Dr. Conti relied on peer-reviewed journal articles, textbooks, studies regarding the economic value of drugs, *see id.* Ex. 17, at ¶ 9 n.15-16, conversations with providers and insurers, *see id.* Ex. 16, at 83:23-84:7, and the generally accepted economic principles of supply and demand in support of her opinion, *see id.* Ex. 15, at ¶ 38 ("There is no equilibrium between the demand for compliant prescription drugs and the supply of non-compliant drugs."). Dr. Conti has therefore provided a sufficient reliable basis and methodology for her expert opinion. *In re Paoli*, 35 F.3d at 744 ("[Proponents of expert testimony] do not have to demonstrate to the judge . . . that the assessments of their experts are correct, they only have to demonstrate . . . that their opinions are reliable."). To the extent GSK argues Dr. Conti's analysis is superficial and conclusory, this argument goes

to the credibility of Dr. Conti's testimony and may be elicited through cross-examination. *See Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) ("[T]he burden of exploring the facts and assumptions underlying the testimony of an expert witness [is placed] on opposing counsel during cross-examination.").

Third, GSK's argument that Dr. Conti merely parrots Plaintiffs' allegations because she lacks real-world experience as a third-party payor is not a reason to exclude Dr. Conti's testimony. GSK points to two lines in Dr. Conti's deposition where she said she is not a third-party payer and has never worked for one. *See* GSK Mot. Ex. 16, at 153:6-8 ("I'm not a third-party payer. I've never worked in a third-party payer"). And GSK argues Dr. Conti has no basis to opine on the value insurers assign to non-complaint drugs. GSK's argument again goes to the credibility and weight of Dr. Conti's testimony, not the admissibility of her opinion. *See Stecyk*, 295 F.3d at 414.

Finally, Dr. Conti's damages calculation is not flawed for not factoring in any rebates Plaintiffs may have received for the At-Issue Drugs or any therapeutic alternatives they may have had to cover as a result of discontinuing coverage for the At-Issue Drugs. GSK's argument that Dr. Conti should have reduced her damages amount—as suggested by GSK's expert Dr. Mohan Rao—is not a basis to exclude Dr. Conti's analysis. Rather, it demonstrates a fact question the jury must resolve because it requires a credibility determination and comparison of each expert's methodology. *Compare* GSK Mot. Ex. 15, at ¶ 43 ("Based on my assessment that spending on prescription drugs cannot be separated from the quality manufacturing assured by the manufacturer and overseen by government regulators, non-compliant prescription drugs have no economic value. Therefore, the appropriate measure of damages in this matter is the total amount paid . . . .") *with* Pls.' Resp. in Opp'n to Def.'s Mot. for Summ. J. Ex. 222, at ¶ 48 ("Dr. Conti fails to account for rebates received by Plaintiffs after the initial reimbursement of a claim, causing her to

overstate Plaintiffs' purchases by approximately 8 percent. She also fails to deduct payments on claims where Plaintiffs served in an administrative role only . . . ."). Accordingly, GSK's motion to exclude Dr. Conti's testimony will be denied. *See In re Asbestos Prods. Liab. Lit. (No. VI)*, 714 F. Supp. 2d 535, 547 (E.D. Pa. 2010) ("[I]t is up to the jury to decide whether the expert used the best or most reliable methodology, what weight to accord to his testimony and which of [the] competing experts' opinions should be credited.").

CONCLUSION

In sum, GSK's motion to exclude will be granted insofar as Dr. Kessler will be precluded from defining "material impact" or referring to certain cGMP violations as having a "material impact" during his testimony at trial, and Dr. Schondelmeyer will be excluded from testifying at trial. The balance of the motion will be denied.

An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, C.J.